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TITLE: Stylet unit for implanting a medical electrode cable

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Abstract Text - ABTX (1):

A stylet unit suitable for stiffening a hollow electrode cable, such as during the introduction and the anchoring of a medical electrode cable in the human body, includes a combination of a pair of flexible, coaxially arranged stylet elements, i.e., a tubular stylet sleeve and an internal stylet, which can be inserted into a channel in the sleeve and whose end section is pre-bent to one side. Both the stylet sleeve channel and moving inner stylet contained therein have sections or segments with non-circular cross-sections, the profile of the stylet's non-circular cross-section, in relation to the profile of the sleeve channel's non-circular cross-section, preventing the stylet from rotating in relation to the surrounding sleeve, at least within the parts of the sleeve in which both the stylet and the sleeve channel have interacting non-circular cross-sections. The stylet sleeve also has a distal end section which is pre-bent in a first lateral direction in relation to the stylet unit, and the inner stylet's distal end section is pre-bent in the diametrically opposite lateral direction. The rotation-preventing non-circular cross-sections ensure that the oppositely pre-bent stylet and sleeve portions remain in the same plane, so the forces respectively produced by each

substantially cancel, thereby facilitating relative movement of the stylet in the sleeve.

Brief Summary Text - BSTX (16):

The above object is achieved in accordance with the principles of the present invention in a stylet unit insertable into a channel in an elongated element, such as a medical electrode cable, the stylet unit including a double stylet combination formed by a flexible, tubular stylet sleeve and an inner stylet insertable into a channel in the stylet sleeve. The stylet has a distal end section which is pre-bent in a plane, and the stylet sleeve and the stylet each have at least one longitudinal section with a non-circular cross-section, the non-circular cross-sections of the sleeve and the stylet being matched in shape so as to prevent rotation of the stylet in the channel of the sleeve.

Brief Summary Text - BSTX (17):

Thus, the most distinctive feature of the stylet unit according to the invention is that the stylet sleeve has at least one longitudinal section or segment within which the sleeve channel has a non-circular cross-section, and the inner stylet, which can move inside the stylet sleeve, has at least one longitudinal section with a non-circular cross-section, and the profile of the stylet's non-circular cross-section, in relation to the profile of the sleeve's non-circular channel cross-section, so that the stylet is prevented from rotating in relation to the surrounding sleeve in the areas of the sleeve in which the stylet and the stylet channel have interacting non-circular cross-sections.

Brief Summary Text - BSTX (19):

The stylet sleeve, for example, could have a first longitudinal section in which the channel has a circular cross-section and a subsequent, second longitudinal section in which the channel has a non-circular cross-section, with the inner moving stylet, which can be inserted into the stylet sleeve, having a non-circular cross-section for most of its length.

In an alternative embodiment, the stylet sleeve channel can have a non-circular cross-section over most of the length of the sleeve, while the inner stylet has a first longitudinal section with a non-circular cross-section, a subsequent second longitudinal section with a circular cross-section and, finally, a third longitudinal section with a non-circular cross-section.

Brief Summary Text - BSTX (20):

From the manufacturing point of view, however, it would be preferable for both the stylet channel and the moveable inner stylet to have a non-circular cross-section over most of their lengths, preventing the stylet from rotating, in relation to the surrounding sleeve, over all of its length.

Detailed Description Text - DETX (6):

When the stylet unit is a conventional double stylet combination, in which both the stylet 6 and the channel of the sleeve 4 have a circular cross-section, retraction of the pre-bent distal end section 18 of the stylet 6 into the straight stylet sleeve 4 (see FIG. 8a) causes the corresponding end section of the sleeve 4 to bend outwardly to one side (see FIG. 8b) because of the pre-tensioning force arising in the sleeve (when the stylet is retracted into the sleeve), thereby forcing the stylet end section 18 to straighten.

Detailed Description Text - DETX (8):

Thus, FIG. 2 shows the stylet unit 22 with the stylet end sections 28 protruding out of the sleeve 24. FIG. 3 shows the stylet unit 22 after the stylet 26 has been axially retracted the stroke distance L out of the support tube 32 and sleeve 24. The circular, pre-bent end section 18 of the stylet 26 has accordingly been fully retracted into the end section of the sleeve 28 so the end stop ball 20 is at the opening of the end section 28. In practice, retraction of the end section 18 into the sleeve section 28 is achieved when the stylet sleeve 24 is slid over the stylet end section 18. Since the distal end section 28 of the sleeve 24 is pre-bent in a direction opposite to the bend of the stylet end section 18, retraction of the stylet end section 18 into the sleeve section 28 causes both pre-bends to cancel each other, enabling the stylet unit 22 to assume the straight configuration shown in FIG. 3. Thus, the "pre-tensioning force", which the stylet end section 18 generates in the sleeve end section 28 when the stylet 26 is retracted into the end section 28, counteracts and cancels the bending of the end section 28 of the sleeve 24 in the opposite direction. For the two bending effects, exerted by the pre-bent end section 28 of the sleeve 24 and the pre-bent end section 18 of the stylet 26, to cancel each other, they must act in opposite directions in the same plane, in this instance in the plane shown in FIG. 2. This requires the inner stylet to be kept from rotating in relation to the surrounding stylet sleeve 24. This rotation-prevention is achieved by providing each of the stylet sleeve 24 and the stylet 26 insertable therein with a non-circular cross-section. In other words, the cross-sectional profile

of the stylet 26 must be such that the stylet 26 is incapable of rotating in the channel of the sleeve 24. For the inner stylet 26 to be able to perform the desired coaxial movement inside the stylet sleeve 24, some tolerance or radial play must be left between the cross-sections of the inner stylet 24 and the stylet channel. In practice, it may be appropriate (as noted above in conjunction with examples supplied of values for the diameter of the inner stylet 26 and its associated stylet sleeve 24) for the stylet 26 and sleeve channel to be dimensioned so radial play between them amounts to at least 0.02 mm.

Detailed Description Text - DETX (17):

In the use of a stylet unit 22 in which both the stylet sleeve channel and its associated, moving inner stylet 26 do not have a non-circular cross-section along the entire length of the stylet unit 22, certain problems can develop because of increased friction between the stylet 26 and stylet sleeve channel, especially in instances in which the entire stylet unit 22 is subjected to extensive bending. When a hollow electrode cable, with an inserted stylet unit 22, is to be introduced into the heart via the venous system, different parts or sections of the electrode cable will be bent to different degrees, as can be seen in the schematic depiction in FIG. 10, which shows an electrode cable 50 with an hand-operated guide 52 for the stylet unit inserted into the electrode cable. The guide 52 is located at the proximal end of the electrode cable 50. Movement of the inner stylet 26 of the stylet unit 22 (not shown here) in relation to its surrounding stylet sleeve 24 is performed by manual movement of a sleeve part 54 of the guide 52 in relation to a tubular part 56 of the guide 52. A practical problem caused by the increased friction

occurring in the bending of the cable 50 is that the use of excessive force may be necessary in order to operate the guide 52.

Detailed Description Text - DETX (18):

The increase in friction in the stylet unit 22 is because of elevated contact pressure between the stylet 26 and interior of the sleeve channel when the stylet buckles inside the stylet sleeve 24 and because of other friction phenomena. The buckling phenomenon can be avoided, however, by providing the stylet sleeve channel and the stylet 26 with a rotation symmetrical cross-section instead of a non-symmetrical (non-circular) cross-section at the points at which the electrode cable 50 must be bent.

Detailed Description Text - DETX (19):

This can be achieved in general when the stylet sleeve channel or the internal stylet have a circular cross-section only in the bent areas. In the first instance, the stylet sleeve channel is devised with a non-circular cross-section only at the location at which compensating must be made for the flexural moment exerted by the stylet on the surrounding stylet sleeve when the stylet is inserted into the sleeve.

Detailed Description Text - DETX (21):

The inner stylet, generally designated 64, for the sleeve 58 according to FIG. 11 is equipped with a circular, pre-bent distal end section 66 of about the same type shown in FIG. 4. In this instance, the stylet 64 has a non-circular cross-section with the dimensions 0.19 mm.times.0.30 mm.

Detailed Description Text - DETX (23):

In this instance, the stylet sleeve, generally designated 68, as shown in FIG. 13, is an externally circular, cylindrical tube but whose internal channel has a non-circular cross-section. Here, the diameter of the sleeve 68 is 0.416 mm, whereas the non-circular cross-section of the sleeve's internal channel is envisaged as being 0.24 mm .times.0.34 mm.

Detailed Description Text - DETX (24):

The inner stylet, generally designated 70, for the stylet sleeve, generally designated 68, according to FIG. 13 and shown in FIG. 14, in this instance has a shorter first stylet section 72 with a non-circular cross-section, a longer second stylet section 74 with a circular cross-section and a pre-bent, distal end section 76 with a non-circular cross-section. In this instance, the stylet sections 72 and 76 are as both 0.20 mm.times.0.31 mm, whereas the stylet section 74 is circular and cylindrical with a 0.19 mm cross-sectional diameter.

Detailed Description Text - DETX (28):

According to FIG. 15c, the parts of the stylet which still have a diameter of 0.30 mm are then worked until these parts have a non-circular cross-section with the dimensions 0.19 mm.times.0.30 mm. The finished stylet is then cut off at points S1--S1 and S2--S2 respectively.

Detailed Description Text - DETX (30):

FIGS. 16 and 17 respectively show different versions of a stylet sleeve 80 for a fourth embodiment of the inventive stylet unit. Each sleeve 80 has a section 81 with a circular cross-section. The sleeve 80 in FIG. 16 has a distal end section 82 with a non-circular cross-section which extends along the entire length of the distal end section 82. In the version

of FIG. 17, the sleeve 80 has a distal end section 82' with a non-circular cross-section, the non-circular cross-section of the distal end section 82 being formed by spaced apart longitudinal sections 88 and 90.

Detailed Description Text - DETX (31):

Each of the sleeves 80 shown in FIGS. 16 and 17 is for use with an inner stylet 84 as shown in FIG. 18. The inner stylet 84 of FIG. 18 has a section 85 with a circular cross-section, and a distal end section 86 with a non-circular cross-section. In this embodiment, the distal end section 86 of the inner stylet 84 is longer than the length of the respective distal end sections 82 and 82' of the two versions of the sleeve 80 shown in FIGS. 16 and 17. Preferably the distal end section 86 of the inner stylet 84 is at least two times longer than the length of the distal end sections 82 and 82'.

Claims Text - CLTX (4):

said sleeve having at least one longitudinal sleeve section in which said channel has a non-circular cross-section, and having a distal sleeve end pre-bent in said plane in an opposite direction to said distal end stylet section; and

Claims Text - CLTX (5):

said stylet having at least one longitudinal stylet section with a non-circular cross-section, the non-circular cross-section of said stylet section being matched to the non-circular cross-section of said sleeve section for preventing rotation of said stylet in said channel of said sleeve while allowing longitudinal movement of said stylet within said channel of said



sleeve.

Claims Text - CLTX (6):

2. A stylet unit as claimed in claim 1 wherein said sleeve has a first longitudinal sleeve section having a circular cross-section, followed in the longitudinal direction by a second longitudinal section comprising said longitudinal sleeve section with a non-circular cross-section, and wherein said stylet has a non-circular cross-section along substantially an entire length of said stylet.

Claims Text - CLTX (7):

3. A stylet unit as claimed in claim 1 wherein said channel of said sleeve has a non-circular cross-section along substantially an entire length of said sleeve, and wherein said stylet has a first longitudinal section with said non-circular cross-section, followed in a longitudinal direction by a second longitudinal section having a circular cross-section, followed in said longitudinal direction by a third longitudinal section having said non-circular cross-section.

Claims Text - CLTX (8):

4. A stylet unit as claimed in claim 1 wherein each of said channel of said sleeve and said stylet have said non-circular cross-section along substantially their entire respective lengths for preventing rotation of said stylet in said channel of said sleeve along the entire length of said stylet.

Claims Text - CLTX (14):

10. A stylet unit as claimed in claim 9 wherein said non-circular cross-section of said stylet is smaller than said

non-circular cross-section of  
said channel so that a tolerance between said non-circular  
cross-sections of  
said stylet and said channel of at least 0.02 mm exists.

Claims Text - CLTX (15):

11. A stylet unit as claimed in claim 1 wherein said  
non-circular  
cross-section of said stylet is smaller than said  
non-circular cross-section of  
said channel so that a tolerance between said non-circular  
cross-sections of  
said stylet and said channel of at least 0.02 mm exists.

Claims Text - CLTX (16):

12. A stylet unit as claimed in claim 1 wherein the  
respective non-circular  
cross-section of said stylet section and said sleeve  
section are selected from  
the group consisting of concentric ovals, concentric  
ellipses and regular  
polygons having rounded corners.

Claims Text - CLTX (21):

17. A stylet unit as claimed in claim 15 wherein said  
longitudinal sleeve  
section has a non-circular cross-section along an entirety  
of its length.

Claims Text - CLTX (22):

18. A stylet unit as claimed in claim 15 wherein said  
longitudinal sleeve  
section comprises at least two spaced-apart longitudinal  
sleeve sub-sections,  
each of said longitudinal sleeve sub-sections having said  
non-circular  
cross-section.

Claims Text - CLTX (26):

a stylet unit, insertable into said channel in said  
cable, said stylet unit  
comprising a stylet sleeve having an interior channel and a  
stylet movable in

said interior channel, said channel of said stylet sleeve having at least a portion thereof with a non-circular cross-section and said stylet having at least a portion thereof with a non-circular cross-section for preventing rotation of said stylet in said channel of said stylet sleeve, and said stylet having a distal stylet end section which is pre-bent in a plane and said sleeve having a distal end;

Current US Class - CLAS (2):  
604

Field Of Search Class - FSC (3):  
604